K072662
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SECTION 5: 510(k) Summary

CHEETAH MEDICAL, INC.

Submitter

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JAN 16 2008

Date Prepared

January 2008

Device Information

Trade name: Cheetah Reliant
Common name: Portable, non-invasive Cardiac Output monitoring device
Classification Name: DSB – (21 CFR 870.2770, "Impedance plethymograph")

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name	Manufacturer
K042144	Cheetah NICOM System	Cheetah Medical, Inc.

Device Description

The Cheetah Reliant is a portable, non-invasive, Cardiac Output measurement system. The Cheetah Reliant measures the Cardiac Output by employing the electrical bio-impedance measurement technique. Electrical bio-impedance is the characteristic impedance of a volume of tissue and fluid. In the case of Cardiac Output measurements, the relevant tissue includes the heart and the immediate surrounding volume of the thorax. The relevant fluid is blood.

Intended Use

The Cheetah Reliant is a portable, non-invasive Cardiac Output monitoring device based on bio-impedance Cardiography. The Cheetah Reliant system is intended to monitor and display a patient's Cardiac Output in units of Ltr/min.

Device Modification

1st generation **Cheetah NICOM System (K042144)** was modified to produce a compact, stand alone version - **Cheetah Reliant**. Modification includes the following: Smaller overall dimensions, the use of an embedded processing unit instead of an external laptop PC, and the addition of an integral LCD display.

A series of bench testing protocols were carried out, throughout the various stages of product development. Final testing included Module level testing, Integration level testing, and finally System level testing. Testing demonstrated the safety and effectiveness of the tested devices.

Validation and verification protocols also included a comparative study of the Reliant performance vs. that of 1st generation NICOM System:

Bench testing, consisting of Raw Data obtained in advance from 44 patients in the Intensive Care unit of Ambroise Pare Hospital in France, as well as testing in the Human (23 volunteers), against 1st generation Nicom. The Bland-Altman showed **symmetrical distribution** for CO measurement differences around the bias, and a **confidence level of 95%**.

Mechanical and EMC testing was conducted per IEC/EN60601-1, UL 60601-1, and CSA C22.2 No. 601.1

Conclusion

The **Cheetah Reliant**, the subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. The device presents no adverse health effects or safety risks to patients when used as intended.

The **Cheetah Reliant** has the same intended use and fundamental scientific technology as the predicate device - 1st generation **Cheetah NICOM System (K042144)**.

The device was extensively tested – both Bench and in the human - against its predicate, and was found to be substantially equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2008

Cheetah Medical, Inc.
c/o Mr. Benny Arazy
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Mizpe Aviv, Industrial Park 13
M.P. Misgav 20187
ISRAEL

Re: K072662
Trade/Device Name: Cheetah Reliant
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: December 5, 2007
Received: December 21, 2007

Dear Mr. Arazy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram Zuckerman, MD
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072662

Device Name: Cheetah Reliant

Indications for Use:

The Cheetah Reliant is a portable, non-invasive Cardiac Output monitoring device based on bio-impedance Cardiography. The Cheetah Reliant system is intended to monitor and display a patient's Cardiac Output in units of Ltr/min.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072662